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510(K) SUMMARY

The 510(k) summary is selected by my Sejoy Electronics & Instruments Co., Ltd for this submission.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: _____

1. **Submitter's Identification:**

Name: SEJOY ELECTRONICS &. INSTRUMENTS CO., LTD
Add.: 4th Floor, B2 Building, Feng-Tan-Lu Industrial Zone, West Lake District, Hangzhou, P. R. China
Tel.: 0086-571-81957767 Fax: 0086-571-81957750
Name of contact person: Mr. Ren Yunhua
Prepared date: November 17, 2007

2. **Name of the Device:**

Trade name: Infrared Ear Thermometer ET-101A
Common name: Clinical Electronic Thermometer
Classification Name: Thermometer, Electronic, Clinical
Class: II
Panel: 80
Procode: FLL- Clinical Electronic Thermometer
Regulation Number: 21 CFR 880.2910

3. **Predicate Device Information:**

* BRAUN THERMOSCAN IRT 4520
510(k) number: K031928
Applicant: BRAUN GMBH
Owner: THE GILLETTE COMPANY

4. **Device Description:**

Infrared Ear Thermometer ET-101A is electronic thermometers using an infrared detector (thermopile detector) to detect body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces of the patient.

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To measure ear temperature, put a new clean probe cover on the infrared ear thermometer, then insert it into a patient's outer ear canal. A test button is pressed to start the measurement through the radiation exchanges. The electrical signal read out from the detector is fed to the circuit for amplification and calculation. The measured temperature then appears on a LCD display. The total operation takes a few seconds.

5. **Intended Use:**

The devices Model ET-101A is intended to measure the human body temperature from the auditory canal. The devices are reusable for home use on people of all ages.

6. **Comparison to Predicate Devices:**

The device Infrared Ear Thermometer ET-101A is similar in design and intended use to BRAUN THERMOSCAN IRT 4520, differing mostly in physical dimensions, display resolution, battery replacement method.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes ASTM E1965-98, as well as IEC60601-1 and IEC60601-1-2 requirements.
Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers.

8. **Discussion of Clinical Tests Performed:**

Controlled human clinical studies were conducted using the Infrared Ear Thermometer ET-101A. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Sejoy Clinical Test Protocol outline.

9. **Conclusions:**

Infrared Ear Thermometer ET-101A has the same intended use and similar technological characteristics as the BRAUN THERMOSCAN IRT 4520. Moreover, information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Ear Thermometer ET-101A is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2008

Sejoy Electronics & Instruments Company, Limited
C/O Mr. Tzu-Wei Li
Responsible Third Party Officer
Center for Measurement Standards/Industrial
Technology Research Institute
Building 16, 321 Kuang Fu Road, Section 2
Hsinchu, Taiwan 30042
REPUBLIC OF CHINA

Re: K082192
Trade/Device Name: Infrared Ear Thermometer ET-101A
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 9, 2008
Received: September 10, 2008

Dear Mr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

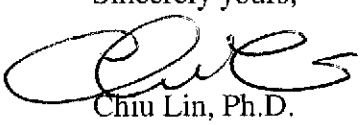
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K982192

Indications for Use

510(k) Number (if known):

Device Name: Infrared Ear Thermometer ET-101A

Indications For Use:

Infrared Ear Thermometer ET-101A is indicated for the intermittent measurement and monitoring of human body temperature by consumers in a home use environment. It's intended for use on people of all ages.

Prescription Use_____ **AND/OR** **Over-The-Counter Use** √
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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